89 and portions of the specification have been amended herein in order to make certain format changes. No claims have been added. Applicant maintains that the changes to the claims and the specification raise no issue of new matter, and respectfully request entry of this amendment. Upon entry of this amendment, claim 89 will be pending and under examination.

Pursuant to the requirements of 37 C.F.R. §1.121, applicant annexes hereto as Exhibit A those paragraphs amended to include SEQ. ID NOs and ATCC Accession Nos. The annexed paragraphs are annotated to show the amendments made herein.

Additionally, pursuant to the requirements of 37 C.F.R. §1.121, applicant annexes hereto as Exhibit B claim 89 as amended. The annexed claim is annotated to show amendments made herein.

In view of the amendments to the claims and specification and the arguments set forth below, applicant maintains that the Examiner's objections and rejections have been overcome, and respectfully request that he reconsider and withdraw same.

Formalities

The Examiner stated that applicant's election with traverse of Group I, claims 88 and 89, made in his November 6, 2000 response to October 6, 2000 Restriction Requirement is acknowledged, but that his traversal of the restriction requirement has not been found persuasive. Accordingly, the Examiner has withdrawn claims 90-92, 98, 102 and 103 from further consideration as drawn to a non-elected invention, there allegedly being no allowable generic or linking claim. Applicant acknowledges the Examiner's remarks.

The Examiner also stated that this application contains sequence disclosures that are encompassed by the definitions for

nucleotide and/or amino acid sequences set forth in 37 C.F.R. §1.821(a)(1) and (a)(2), and that the application fails to comply with the requirements of 37 C.F.R. §1.821 through §1.825. Specifically, the Examiner stated that the specification contains applicable sequences in Figures 2B, 5B-1, 5B-2, 5B-3, 6A and 6B, and that these sequences have not been properly identified by sequence identifiers in the specification. The Examiner also stated that there are references to ATCC deposits where no deposit number is disclosed.

In response, applicant points out that these informalities have been corrected by amendment herein.

35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 88 and 89 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First, the Examiner asserted that the language of claim 89 is unclear, since there is no Figure 5B, *per se*, but rather Figures 5B-1, 5B-2 and 5B-3.

In response, applicant respectfully traverses the Examiner's rejection. Claim 89, as amended, provides a purified human MUM-1 protein, and no longer recites "Figure 5B." Applicant maintains that the scope of amended claim 89 is clear, in that the claimed protein is identified by species, and is clearly exemplified by the amino acid sequence shown in SEQ ID NO:14. Thus, applicant maintains that claim 89, as amended, overcomes the stated grounds for rejection.

Second, the Examiner asserted that the scope of claim 88 is unclear.

In response, applicant points out that claim 88 has been canceled, thereby rendering the Examiner's rejection thereof moot.

In view of the above remarks, applicant maintains that claim 89 satisfies the requirements of 35 U.S.C. §112, second paragraph.

Rejection Under 35 U.S.C. §102(a)

The Examiner rejected claims 88 and 89 under 35 U.S.C. §102(a) as allegedly anticipated by Matsuyama, et al. Applicant again points out that claim 88 has been canceled, thereby rendering the rejection thereof moot.

In response to the Examiner's rejection of claim 89, applicant respectfully traverses.

Applicant claims a purified human MUM-1 protein. Matsuyama, et al. fail to teach this protein. Instead, Matsuyama, et al. relate to a murine protein. Specifically, Matsuyama, et al. disclose the sequence upstream of a mouse LSIRF-encoding region. Matsuyama, et al. also disclose a few nucleotides of the LSIRF protein-encoding sequence, but do not disclose the entire LSIRF protein-encoding sequence.

Applicant also points out that, contrary to the Examiner's position, Matsuyama, et al. fail to teach the Western blot detection of anything but murine LSIRF protein. Indeed, Matsuyama, et al. performed this detection using antisera against an amino acid sequence completely absent from the claimed protein.

The Examiner also asserted that on page 40 of the instant specification, applicant concedes that the "gene" disclosed by Matsuyama, et al. "is the same as the instantly claimed `MUM-1'".

While again traversing the Examiner's point regarding Matsuyama, et al., this statement on page 40 of the specification in fact refers to the protein of Grant, et al. (identified as reference 26), and not the protein of Matsuyama, et al. (identified as reference 27). A copy of Grant, et al. is annexed hereto as Exhibit C. Moreover, the protein referred to in Grant, et al., termed "cIRF-3" and encoded by the gene sequence deposited in Genbank under accession number U20338, is a chicken protein that differs in size and sequence from the claimed human protein. A copy of Genbank submission number U20338 is annexed hereto as Exhibit D. Applicant further notes that the human proteins having Genbank-deposited sequences referred to in the legend for Figure 1 of Grant, et al., namely IRF-1, IRF-2 and ICSBP, also differ from the claimed human protein. These differences are explicitly described on page 40, lines 1-28 of the specification.

In sum, applicant maintains that neither Grant, et al. nor Matsuyama, et al. teach applicant's human MUM-1 protein. Accordingly, applicant maintains that claim 89 satisfies the requirements of 35 U.S.C. §102(a).

Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claim 88 under 35 U.S.C. §112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor had possession of the claimed invention.

In response, applicant again points out that claim 88 has been canceled herein, thereby rendering the Examiner's rejection moot.

Rejection Under 35 U.S.C. §101

The Examiner rejected claims 88 and 89 under 35 U.S.C. §101 because the claimed invention allegedly is not supported by either a specific utility or a well established, i.e. credible, utility.

In response, applicant respectfully traverses the Examiner's rejection. As already stated, applicant has canceled claim 88, thereby rendering the Examiner's rejection of this claim moot.

In response to the Examiner's rejection of claim 89, applicant respectfully traverses.

Claim 89 provides an isolated human MUM-1 protein. In this application, applicant establishes that over-expression of the MUM-1 gene (i.e. over-production of MUM-1 mRNA) correlates with multiple myeloma. Absent a showing to the contrary, one of skill would reasonably conclude that over-production of MUM-1 protein would accompany over-production of its corresponding mRNA. Hence, applicant has demonstrated that over-production of MUM-1 protein correlates with multiple myeloma, and the Examiner has provided no factual basis for concluding otherwise.

Detecting the over-production of MUM-1 protein provides a means of diagnosing multiple myeloma. The instant protein is useful in this regard, in that it can be used to generate anti-MUM-1 antibodies through established means, while these antibodies in turn can be used to diagnose multiple myeloma in a subject. In short, the claimed protein has a specific and credible utility, because it is useful for stimulating anti-MUM-1 antibody production, which in turn permits the diagnosis of multiple myeloma.

Given the nature of the claimed invention, applicant maintains

that, contrary to the Examiner's assertion, knowledge of the claimed protein's biological activity is not required to demonstrate its utility. That is, the claimed protein is useful because, *inter alia*, its over-production is correlative with multiple myeloma. As a result, determining this overproduction is all that diagnosing multiple myeloma requires. Any further understanding of MUM-1 protein's function is irrelevant for such purposes.

In view of the above remarks, applicant maintains that claim 89 satisfies the requirements of 35 U.S.C. §101.

Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 88 and 89 under 35 U.S.C. §112, first paragraph. Specifically, the Examiner asserted that since the claimed invention is not supported by either an asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention. As mentioned above, applicant has canceled claim 88 without introducing any new claim corresponding thereto, thereby rendering moot the Examiner's remarks concerning said claim.

In response to the rejection of claim 89, applicant respectfully traverses the Examiner's rejection. As discussed above, the claimed protein has utility in that detecting its over-production permits the diagnosis of multiple myeloma. Since making the claimed protein and using it to generate antibodies requires only routine materials and methods, applicant maintains that one of ordinary skill would know how to make and use the claimed protein.

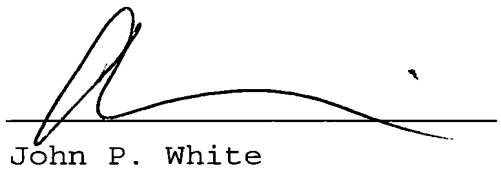
In view of the above remarks, applicant maintains that claim 89, as amended, satisfies the requirements of 35 U.S.C. §112, first

paragraph.

If a telephone conference would be of assistance in advancing the prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, except for the $55.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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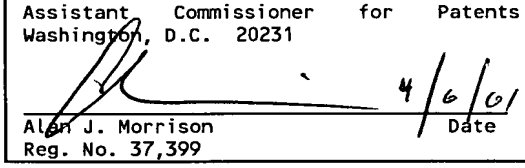

4/6/01
Alan J. Morrison Date
Reg. No. 37,399

The paragraph on page 19, lines 6-15:

(Amended) In an embodiment, a cDNA nucleic acid molecule encoding a MUM-1 protein is cloned into a pBluescript KS+ and the resulting plasmid is designated as pcMUM1-1.6a (ATCC Accession No. 97579). Plasmid pcMUM1-1.6a was deposited on May 28, 1996 with the American Type Culture Collection (ATCC), 12301 Parklawn Drive, Rockville, Maryland 20852, U.S.A. under the provisions of the Budapest Treaty for the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. Plasmid pcMUM1-1.6a was accorded ATCC Accession Number 97579.

The paragraph on page 19, lines 17-27:

(Amended) In another embodiment, a partial cDNA nucleic acid molecule encoding a MUM-1 protein is cloned into a pBluescript KS+ and the resulting plasmid is designated as pMUM1-2.4B/N (ATCC Accession No. 97578). Plasmid pMUM1-2.4B/N was deposited on May 28, 1996 with the American Type Culture Collection (ATCC), 12301 Parklawn Drive, Rockville, Maryland 20852, U.S.A. under the provisions of the Budapest Treaty for the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. Plasmid pMUM1-2.4B/N was accorded ATCC Accession Number 97578.

The paragraph on page 19, lines 29 through page 20, line 5:

(Amended) In another embodiment, a partial cDNA nucleic acid molecule encoding a MUM-1 protein is cloned into a pBluescript KS+ and the resulting plasmid is designated as pMUM1-7.7B (ATCC Accession No. 97577). Plasmid pMUM1-7.7B was deposited on May 28, 1996 with the American Type Culture Collection (ATCC), 12301 Parklawn Drive, Rockville, Maryland 20852, U.S.A. under the provisions of the Budapest Treaty for the International Recognition of the Deposit of Microorganisms for

the Purposes of Patent Procedure. Plasmid pMUM1-7.7B was accorded ATCC Accession Number 97577.

The paragraph on page 20, lines 7-16:

(Amended) In another embodiment, a partial cDNA of the nucleic acid molecule encoding a MUM-2 protein is cloned into a pBluescript KS+ and the resulting plasmid is designated as pMUM2-8 (ATCC Accession No. 97580). Plasmid pMUM2-8 was deposited on May 28, 1996 with the American Type Culture Collection (ATCC), 12301 Parklawn Drive, Rockville, Maryland 20852, U.S.A. under the provisions of the Budapest Treaty for the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. Plasmid pMUM2-8 was accorded ATCC Accession Number 97580.

The paragraph on page 20, lines 18-20:

(Amended) In an embodiment, the isolated DNA molecule encoding a MUM protein is a cDNA molecule having the nucleotide sequence shown in [Figure] Figures 5B-1 through 5B-3 (SEQ. ID NO:13).

The paragraph on page 20, lines 31 through page 21, line 6:

(Amended) In an embodiment, the isolated nucleic molecule encodes the a human MUM-1 protein having substantially the same amino acid sequence as shown in [Figure] Figures 5B-1 through 5B-2 (SEQ. ID NO :14). In [an] another embodiment, the isolated nucleic molecule encodes a human MUM-1 protein having the same amino acid sequence as shown in [Figure] Figures 5B-1 through 5B-2 (SEQ. ID NO:14). In [an] another embodiment, the isolated nucleic acid molecule encoding a MUM protein is operatively linked to a promoter of RNA transcription.

(Amended) A purified human MUM-1 protein [of claim 88, wherein the MUM-1 protein has the same amino acid sequence as shown in Figure 5B (SEQ. ID NO:14)].